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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,062	03/22/2004	Aled Edwards	IPT-101.01	1510

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PATENT GROUP, WORLD TRADE CENTER WEST
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EXAMINER	
NOAKES, SUZANNE MARIE	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/806,062	EDWARDS ET AL.	
	Examiner	Art Unit	
	Suzanne M. Noakes, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *1-22 and 24-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence Alignements*.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group IV, claim 23 in the reply filed on 13 July 2006 is acknowledged. The traversal is on the ground(s) that there is no undue or divergent search required to search all of the Groups together because each group is classified in the same class and sub-class. This is not found persuasive because each group is representative of a unique and distinct polypeptide which possesses its own unique primary, secondary, tertiary and quaternary structures which necessarily dictates each polypeptides unique function as well. Thus, there is no co-extensive search which would inclusively search all of the claimed SEQ ID Nos: from the simple search of just one of them. This therefor equates a divergent and burdensome search.

The requirement is still deemed proper and is therefore made FINAL.

Status of the Claims

2. Claims 1-50 are pending. Claims 1-22 and 24-50 are withdrawn from consideration as they are directed to non-elected subject matter. Claim 23 is under examination and the subject of the remainder of this Office action.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: UDP-N-acetylmuramate-alanine ligase polypeptides from *S. aureus*.

4. The Abstract is objected to for not completely describing the disclosed subject matter (see M.P.E.P. § 608.01(b)). It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. A new substitute specification is required which clearly reflects the nature of the claimed invention to which the Application is directed.

Claim Rejections - 35 USC § 112 – 2nd paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 23 is indefinite because it is drawn to a polynucleotide that hybridizes under "stringent conditions". Stringent conditions are not defined by the claim (which reads on the full range of stringent conditions, that is from very permissive to very high stringency). Furthermore, the specification contemplates only generic stringent conditions for all polypeptides but it does not provide a limited definition for ascertaining the requisite degree of stringent conditions sought in the claims and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention and would not be able to determine the metes and bounds of the claims.

Claim Rejections - 35 USC § 112 – 1st paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description:

8. Claims 23 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claim is drawn to isolated polypeptide having at least about 90% sequence identity to SEQ ID No: 28 or 30. The claim does not require that the polypeptide possess any particular conserved structure (which is essential to its activity) or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of amino acids that are defined only by sequence identity or hybridization ability of the DNA which encodes the protein.

The MPEP states that written description for a genus can be achieved by a representative number of species within a broad genus. Claim 23 is broadly generic to all possible variants of a polypeptides comprising SEQ ID No: 28 or 30 that are at least about 90% identical so said SEQ ID No's, or of all possible variants of these polypeptides that are encoded by a polynucleotide which can bind under stringent hybridization conditions to a polynucleotide encoding said SEQ ID Nos, which has the biological activity of UDP-N-acetylmuramate-alanine ligase from *S. aureus*. Thus, the possible variations are enormous to any class of potential UDP-N-acetylmuramate-

alanine ligase recombinant variant polypeptides of SEQ ID No: 28 or 30 with different structure and/or varying degrees of functionality. Since the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of SEQ ID No: 28 or 30 polypeptides that have UDP-N-acetylmuramate-alanine ligase activity beyond that disclosed in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus since the specification does not provide a sufficient number of examples of variants comprising SEQ ID Nos: 28 or 30 which have UDP-N-acetylmuramate-alanine ligase activity.

While having written description of the polypeptide comprising SEQ ID No: 10 identified in the specification and examples, the specification is limited to a select few polypeptides that may qualify under the broad genus but this is in no way indicative or representative of the broad genus because the number of possibilities extend into the thousands.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals

appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). *Vas-Cath Inc. V. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed."* Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Scope of Enablement:

9. Claim 23 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID Nos: 28 or 30 which has UDP-N-acetylmuramate-alanine ligase activity and is from *S. aureus*, does not reasonably provide enablement for variants that are at least 90% identical to SEQ ID No: 28 and 30. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claim is directed to a composition comprising an isolated protein having UDP-N-acetylmuramate-alanine ligase activity comprising the amino acid sequence set forth in SEQ ID Nso: 28 or 30 or biologically active variants thereof having an amino acid sequence at least 90% identical to the amino acid sequence given in SEQ ID Nos: 28 or 30. The specification discloses the isolated proteins consisting of the amino acid

sequence set forth in SEQ ID No: 28 or 30 and the specification further establishes that said polypeptides have UDP-N-acetylmuramate-alanine ligase activity and provides general guidance regarding assays for activity of any protein. General guidance is also given regarding how to make and test variants of any protein. The scope of patent protection sought by Applicant as defined by the claims fails to correlate reasonably with the scope of enabling disclosure set forth in the specification for the following reasons. The problem of prediction protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. While it is known that many amino acid substitutions are generally possible in any given protein the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable of success is limited. Certain positions in the sequence are critical to the protein's structure/function relationship, such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. Particular regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions as all (see Bowie et al. pp. 1306-10, specifically p. 1306 column 2, paragraph 2; Wells pp. 8509-8517). However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein which are tolerant to change (e.g. by amino acid substitutions or deletions or insertions), and the nature and extent of changes that can be made in these positions. Although the specification outlines art-recognized

procedures for producing and screening for active protein variants, this is not adequate guidance as to the nature of active derivatives that may be constructed, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. Even if an active or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon the surrounding residues; therefore substitution or non-essential residues can often destroy activity. Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and screen the same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to the same, the complex nature of the invention, the state of the prior art which established the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claim 23 is rejected under 35 U.S.C. 102(e) as being anticipated by Kunsch et al. (US 6,737,248).

The claim is drawn to a composition containing an isolated recombinant polypeptide of SEQ ID No: 28 or 30, that is at least about 90% identical thereto, or a polypeptide which encoded by polynucleotide which can hybridize under stringent conditions to a polynucleotide of SEQ ID No: 27 or 29.

Kunsch et al. teach a polynucleotide that would encode a polypeptide that is 100% identical to SEQ ID Nos: 28 and 30 (see attached sequence alignment) and claims 1(f), 3, 10 and 19. Claim 1(f) states the ORF 2 of SEQ ID No: 392 and encodes nucleotides 594-1940; as can be seen from the sequence alignment this sequence encompasses and encodes for a polypeptide that is 100% identical to SEQ ID Nos: 28 and 30; claim 3 recites the polynucleotide of claim 1 that encodes a polypeptide; claim 10 recites culturing, expressing and recovering said polypeptide. Claim 19 recites

specific stringent hybridization conditions to which another polynucleotide would be able to hybridize to. Thus the polynucleotide would be able to hybridize under stringent conditions to the polynucleotides of SEQ ID Nos: 27 and 29. Thus, since the claim language of the instant claim uses the alternative, each and every element of the instant claim need not necessarily be anticipated for the entire claim to be anticipated.

12. Claim 23 is rejected under 35 U.S.C. 102(e) as being anticipated by Choi (US 2003/00496648).

The claim is drawn to the composition described in Section 11 of this Office action. Choi teaches an isolated polypeptide comprising an amino acid according to those listed in Table 1, of which SEQ ID No: 2, is 98.4% identical to SEQ ID No: 28 and 30 of the instant application. Furthermore, a vaccine composition comprising said sequence is also taught which suggests extremely pure polypeptides, and on p. 66, paragraph 451, the purity of the protein in Choi's purification protocol teaches a composition of purified, refolded and active proteins that are 95% pure as assessed by SDS-Page gel electrophoresis. Thus, each limitation of the claim has been anticipated.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Noakes, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 7.30am to 4.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SMN
26 July 2006

JON WEBER
SUPERVISORY PATENT EXAMINER

Seq ID 28

RESULT 5
AR535830
LOCUS AR535830 2424 bp DNA linear PAT 08-OCT-2004
DEFINITION Sequence 392 from patent US 6737248. Kunsch et al
ACCESSION AR535830
VERSION AR535830.1 GI:53927047
KEYWORDS .
SOURCE Unknown.
ORGANISM Unknown.
Unclassified.
REFERENCE 1 (bases 1 to 2424)
AUTHORS Kunsch,C.A., Choi,G.A., Barash,S.C., Dillon,P.J., Fannon,M.R. and Rosen,C.A.
TITLE Staphylococcus aureus polynucleotides and sequences
JOURNAL Patent: US 6737248-A 392 18-MAY-2004;
Human Genome Sciences, Inc.; Rockville, MD
FEATURES Location/Qualifiers
source 1. .2424
/organism="unknown"
/mol_type="genomic DNA"
ORIGIN

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Score:	444.00	Matches:	444
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Best Local Similarity:	100.0%	Mismatches:	0
Query Match:	100.0%	Indels:	0
DB:	2	Gaps:	0

US-10-806-062-28 (1-444) x AR535830 (1-2424)

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Qy          1 MetSerLysGluPheTyrIleMetThrHisTyrHisPheValGlyIleLysGlySerGly 20
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        606 ATGAGTAAGGAGTTTTATATAATGACACACTATCATTTTGTCGGAATTAAAGGTTCTGGC 665

Qy         21 MetSerSerLeuAlaGlnIleMetHisAspLeuGlyHisGluValGlnGlySerAspIle 40
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        666 ATGAGTTCATTAGCACAAATCATGCATGATTTAGGACATGAAGTTCAAGGATCGGATATT 725

Qy         41 GluAsnTyrValPheThrGluValAlaLeuArgAsnLysGlyIleLysIleLeuProPhe 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Qy         61 AspAlaAsnAsnIleLysGluAspMetValValIleGlnGlyAsnAlaPheAlaSerSer 80
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Qy         81 HisGluGluIleValArgAlaHisGlnLeuLysLeuAspValValSerTyrAsnAspPhe 100
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Qy        101 LeuGlyGlnIleIleAspGlnTyrThrSerValAlaValThrGlyAlaHisGlyLysThr 120
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Qy        121 SerThrThrGlyLeuLeuSerHisValMetAsnGlyAspLysLysThrSerPheLeuIle 140
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Qy        181 AspHisProAspTyrPheLysAspIleAsnAspValPheAspAlaPheGlnGluMetAla 200
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Qy        201 HisAsnValLysLysGlyIleIleAlaTrpGlyAspAspGluHisLeuArgLysIleGlu 220
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Qy        221 AlaAspValProIleTyrTyrTyrGlyPheLysAspSerAspAspIleTyrAlaGlnAsn 240
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Qy        241 IleGlnIleThrAspLysGlyThrAlaPheAspValTyrValAspGlyGluPheTyrAsp 260
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Qy        261 HisPheLeuSerProGlnTyrGlyAspHisThrValLeuAsnAlaLeuAlaValIleAla 280
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Qy        281 IleSerTyrLeuGluLysLeuAspValThrAsnIleLysGluAlaLeuGluThrPheGly 300
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Qy        301 GlyValLysArgArgPheAsnGluThrThrIleAlaAsnGlnValIleValAspAspTyr 320
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Db       1506 GGTGTTAAACGTCGTTTCAATGAAACTACAATTGCAAATCAAGTTATTGTAGATGATTAT 1565

Qy        321 AlaHisHisProArgGluIleSerAlaThrIleGluThrAlaArgLysLysTyrProHis 340
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Db       1566 GCACACCATCCAAGAGAAATTAGTGCTACAATTGAAACAGCACGAAAGAAATATCCACAT 1625

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Qy        381 IleArgGluAsnThrGlyAlaLeuThrIleGlnAspLeuIleAspLysIleGluGlyAla 400
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Qy        401 SerLeuIleAsnGluAspSerIleAsnValLeuGluGlnPheAspAsnAlaValIleLeu 420
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Qy        421 PheMetGlyAlaGlyAspIleGlnLysLeuGlnAsnAlaTyrLeuAspLysLeuGlyMet 440
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Qy        441 LysAsnAlaPhe 444
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Db       1926 AAAAATGCGTTT 1937
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102(e)

Seq Id 28

RESULT 5
US-10-084-205-2
; Sequence 2, Application US/10084205
; Publication No. US20030049648A1 Choi et al.
; GENERAL INFORMATION:
; APPLICANT: Choi, Gil
; TITLE OF INVENTION: 37 Staphylococcus aureus Genes and Polypeptides
; FILE REFERENCE: PB515P1
; CURRENT APPLICATION NUMBER: US/10/084,205
; CURRENT FILING DATE: 2002-02-28
; PRIOR APPLICATION NUMBER: PCT/US00/23773
; PRIOR FILING DATE: 2000-08-31
; PRIOR APPLICATION NUMBER: 60/151,933
; PRIOR FILING DATE: 1999-09-01
; NUMBER OF SEQ ID NOS: 74
; SOFTWARE: PatentIn Ver. 3.1
; SEQ ID NO 2
; LENGTH: 437
; TYPE: PRT
; ORGANISM: Staphylococcus aureus
US-10-084-205-2

Query Match 98.4%; Score 2275; DB 4; Length 437;
Best Local Similarity 100.0%; Pred. No. 8.7e-180;
Matches 437; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy          8 MTHYHFVGIKGSGMSSLAQIMHDLGHEVQGSDIENYVFTEVALRNKGIKILPFDANNIKE 67
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Qy         68 DMVVIQGNAFASSHEEIVRAHQLKLDVVSYNDFLGQIIDQYTSVAVTGAHGKTSTTGLLS 127
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Qy        248 TAFDVYVDGEFYDHFLSPQYGDHTVLNALAVIAISYLEKLDVTNIKEALETFGGVKRRFN 307
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Db        241 TAFDVYVDGEFYDHFLSPQYGDHTVLNALAVIAISYLEKLDVTNIKEALETFGGVKRRFN 300

Qy        308 ETTIANQVIVDDYAHHPREISATIETARKKYPHKEVVAVFQPHTFSRTQAFLNEFAESLS 367
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 ETTIANQVIVDDYAHHPREISATIETARKKYPHKEVVAVFQPHTFSRTQAFLNEFAESLS 360
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Qy        368 KADRVFLCEIFGSIRENTGALTIQDLIDKIEGASLINEDSINVLEQFDNAVILFMGAGDI 427
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Db        361 KADRVFLCEIFGSIRENTGALTIQDLIDKIEGASLINEDSINVLEQFDNAVILFMGAGDI 420

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Db        421 QKLQNAYLDKLGMKNAF 437
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-continued

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Asn Pro Lys Phe Asp Ser Lys Ser Lys Arg Ser Lys Gly Tyr Ser Ser
                485                 490                 495

Lys Lys Lys Ser Thr Lys Lys Phe Asp Arg Lys Glu Lys Ser Ser Gly
            500                 505                 510

Gly Ser Arg Pro Met Lys Gly Arg Thr Phe Ala Asp His Gln
        515                 520                 525
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What is claimed is:

1. An isolated nucleic acid molecule comprising a polynucleotide having a nucleotide sequence selected from the group consisting of:

(a) a nucleotide sequence encoding any one of the amino acid sequences of the polypeptides shown in Table 1; or

(b) a nucleotide sequence complementary to any one of the nucleotide sequences in (a).

(c) a nucleotide sequence at least 95% identical to any one of the nucleotide sequences shown in Table 1; or,

(d) a nucleotide sequence at least 95% identical to a nucleotide sequence complementary to any one of the nucleotide sequences shown in Table 1.

2. An isolated nucleic acid molecule of claim 1 comprising a polynucleotide which hybridizes under stringent hybridization conditions to a polynucleotide having a nucleotide sequence identical to a nucleotide sequence in (a) or (b) of claim 0.1.

3. An isolated nucleic acid molecule of claim 1 comprising a polynucleotide which encodes an epitope-bearing portion of a polypeptide in (a) of claim 1.

4. The isolated nucleic acid molecule of claim 3, wherein said epitope-bearing portion of a polypeptide comprises an amino acid sequence listed in Table 4.

5. A method for making a recombinant vector comprising inserting an isolated nucleic acid molecule of claim 1 into a vector.

6. A recombinant vector produced by the method of claim 5.

7. A host cell comprising the vector of claim 6.

8. A method of producing a polypeptide comprising:

(a) growing the host cell of claim 7 such that the protein is expressed by the cell; and

(b) recovering the expressed polypeptide.

9. An isolated polypeptide comprising an amino acid sequence selected from the group consisting of:

(a) a complete amino acid sequences of Table 1;

(b) a complete amino acid sequence of Table 1 except the N-terminal residue;

(c) a fragment of a polypeptide of Table 1 having biological activity; and

(d) a fragment of a polypeptide of Table 1 which binds to an antibody specific for a *S. aureus* polypeptide.

10. An isolated polypeptide comprising an amino acid sequence at least 95% identical to an amino acid sequence of Table 1.

11. An isolated epitope-bearing polypeptide comprising an amino acid sequence of Table 4.

12. An isolated antibody specific for the polypeptide of claim 9.

13. A host cell which produces an antibody of claim 12.

14. A vaccine, comprising:

(1) one or more *S. aureus* polypeptides selected from the group consisting of a polypeptide of claim 9; and

(2) a pharmaceutically acceptable diluent, carrier, or excipient;

wherein said polypeptide is present, in an amount effective to elicit protective antibodies in an animal to a member of the Slaphylococcus genus.

15. A method of preventing or attenuating an infection caused by a member of the Staphylococcus genus in an animal, comprising administering to said animal a polypeptide of claim 9, wherein said polypeptide is administered in an amount effective to prevent or attenuate said infection.

16. A method of detecting Staphylococcus nucleic acids in a biological sample comprising:

(a) contacting the sample with one or more nucleic acids of claim 1, under conditions such that hybridization occurs, and

(b) detecting hybridization of said nucleic acids to the one or more Staphylococcus nucleic acid sequences present in the biological sample.

17. A method of detecting Staphylococcus nucleic acids in a biological sample obtained from an animal, comprising:

(a) amplifying one or more Staphylococcus nucleic acid sequences in said sample using polymerase chain reaction, and

(b) detecting said amplified Staphylococcus nucleic acid.

18. A kit for detecting Staphylococcus antibodies in a biological sample obtained from an animal, comprising

(a) a polypeptide of claim 9 attached to a solid support; and

(b) detecting means.

19. A method of detecting Staphylococcus antibodies in a biological sample obtained from an animal, comprising

(a) contacting the sample with a polypeptide of claim 9; and

(b) detecting antibody-antigen complexes.

20. A method of detecting a polypeptide of claim 9 comprising:

(a) obtaining a biological sample suspected of containing said polypeptide; and

(b) determining the presence or absence of said polypeptide in said biological sample.

21. The method of claim 20, wherein said method comprises a step of contacting the sample with an antibody.

* * * * *

Seq Id 30 102(e)

RESULT 5
US-10-084-205-2
; Sequence 2, Application US/10084205
; Publication No. US20030049648A1 Choi
; GENERAL INFORMATION:
; APPLICANT: Choi, Gil
; TITLE OF INVENTION: 37 Staphylococcus aureus Genes and Polypeptides
; FILE REFERENCE: PB515P1
; CURRENT APPLICATION NUMBER: US/10/084,205
; CURRENT FILING DATE: 2002-02-28
; PRIOR APPLICATION NUMBER: PCT/US00/23773
; PRIOR FILING DATE: 2000-08-31
; PRIOR APPLICATION NUMBER: 60/151,933
; PRIOR FILING DATE: 1999-09-01
; NUMBER OF SEQ ID NOS: 74
; SOFTWARE: PatentIn Ver. 3.1
; SEQ ID NO 2
; LENGTH: 437
; TYPE: PRT
; ORGANISM: Staphylococcus aureus
US-10-084-205-2

Query Match 98.4%; Score 2275; DB 4; Length 437;
Best Local Similarity 100.0%; Pred. No. 8.7e-180;
Matches 437; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy          8 MTHYHFVGIKGSGMSSLAQIMHDLGHEVQGSDIENYVFTEVALRNKGIKILPFDANNIKE 67
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Db          1 MTHYHFVGIKGSGMSSLAQIMHDLGHEVQGSDIENYVFTEVALRNKGIKILPFDANNIKE 60

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Db        121 HVMNGDKKTSFLIGDGTGMGLPESDYFAFEACEYRRHFLSYKPDYAIMTNIDFDHPDYFK 180

Qy        188 DINDVFDAFQEMAHNVKKGIIAWGDDEHLRKIEADVPIYYYGFKDSDDIYAQNIQITDKG 247
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Db        181 DINDVFDAFQEMAHNVKKGIIAWGDDEHLRKIEADVPIYYYGFKDSDDIYAQNIQITDKG 240

Qy        248 TAFDVYVDGEFYDHFLSPQYGDHTVLNALAVIAISYLEKLDVTNIKEALETFGGVKRRFN 307
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Db        241 TAFDVYVDGEFYDHFLSPQYGDHTVLNALAVIAISYLEKLDVTNIKEALETFGGVKRRFN 300

Qy        308 ETTIANQVIVDDYAHHPREISATIETARKKYPHKEVVAVFQPHTFSRTQAFLNEFAESLS 367
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 ETTIANQVIVDDYAHHPREISATIETARKKYPHKEVVAVFQPHTFSRTQAFLNEFAESLS 360
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Qy        368 KADRVFLCEIFGSIRENTGALTIQDLIDKIEGASLINEDSINVLEQFDNAVILFMGAGDI 427
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 KADRVFLCEIFGSIRENTGALTIQDLIDKIEGASLINEDSINVLEQFDNAVILFMGAGDI 420

Qy        428 QKLQNAYLDKLGMKNAF 444
              |||||||||||||||||
Db        421 QKLQNAYLDKLGMKNAF 437
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